

## ZEUS Scientific Announces FDA Clearance for ZEUS ELISA™ Borrelia VlsE-1/pepC10 IgG/IgM Test System

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ZEUS Scientific announces it has received clearance from the U.S. Food and Drug Administration (FDA) to market the ZEUS ELISA™ Borrelia VlsE-1/pepC10 IgG/IgM Test System, product code 3Z9661. This new test system is intended for the qualitative detection of IgG and IgM class antibodies to VlsE-1 and pepC10 antigens from *Borrelia burgdorferi* in human serum. The assay is intended for testing serum samples from symptomatic patients or those with Lyme Borreliosis.

Lyme disease is transmitted by the bite of a tick infected with *Borrelia burgdorferi*. Lyme disease continues to be the fastest-growing infectious disease in the United States, with as many as 30,000 confirmed and probable cases reported in a year to the Centers for Disease Control (CDC).

Like the majority of ZEUS ELISA™ test kits, the ZEUS ELISA™ Borrelia VlsE-1/pepC10 IgG/IgM Test is capable of being run in a manual, semi-automated, or fully automated capacity. As with most ZEUS ELISA™ test kits, the ZEUS ELISA™ Borrelia VlsE-1/pepC10 IgG/IgM Test System uses SAVE Diluent® which changes color when sample is added thus ensuring result integrity and eliminating errors from missed samples.

ZEUS Scientific was the first company to obtain FDA clearance for a serological Borrelia assay in the United States. ZEUS Scientific also manufactures ZEUS ELISA™ Borrelia burgdorferi IgG, IgM, and IgG/IgM test systems as well as ZEUS IFA Borrelia burgdorferi IgG, IgM, and IgG/IgM test systems. The ZEUS ELISA™ Borrelia VlsE-1/pepC10 IgG/IgM Test System is available for sale through the ZEUS Scientific global distribution network.

To view a complete listing of ZEUS Scientific diagnostic test solutions, please visit [www.zeusscientific.com/products](http://www.zeusscientific.com/products) for details.

### **About ZEUS Scientific (<http://www.zeusscientific.com>):**

ZEUS Scientific has over 35 years of experience in developing, manufacturing and marketing *in vitro* diagnostic laboratory tests. No other company offers the breadth and depth of products across both autoimmune disease and infectious serology testing, across three methodologies: IFA, ELISA and multiplex (AtheNA Multi-Lyte). ZEUS Scientific is based in Branchburg, New Jersey and markets test systems around the globe through an extensive distribution network. ZEUS Scientific complies with international standard ISO 13485 (2003), Health Canada Medical Device Regulations (SOR/98-282, May 7 1998), the FDA Quality System Regulations (FDA Quality System Regulation, 1996: 21 CFR § 820) and the IVD 98/79/EEC.